

Remarks

Reconsideration of the above identified application is respectfully requested. Claims 1-4 and 6-8 have been rejected under 35 U.S.C. § 102(b) as being anticipated by the Cardinal et al reference. The Examiner has stated that the Cardinal et al reference teaches a matrix comprising a chitosan and a dispersed molecule. The molecule must be dispersed or released for some pharmacological activity. The chitosan matrix in the Cardinal et al reference must be porous to allow the filling and release of the macromolecule. It is stated in the summary of the invention at line 41-51 of the reference, a clear teaching of the invention:

According to the invention, a composition for controlled and prolonged release of at least one macromolecular compound is provided, said composition comprising a porous matrix of chitosan having dispersed therein said macromolecular compound.

The invention also provides a method of administering a pharmacological macromolecular compound by injecting or implanting in a subject in need of treatment a porous chitosan matrix having dispersed therein said macromolecular compound.

In addition, the specification further describes a slow and prolonged release of a pharmacological macromolecular compound, clearly, the object of the invention, at col. 1, line 55 through col. 2, line 7 as follows:

The compositions of the invention are particularly useful when injected or implanted in living tissue for slow and prolonged release of pharmacological macromolecular compounds. The continued release of drugs over a long time period following a single administration has significant practical advantages. However, the composition may also be used in extracorporeal applications such, as medical instruments, e.g. kidney dialysis machines. In such instruments, release of macromolecular compounds may be advantageous, e.g. release of heparin into blood during kidney dialysis.

This invention is applicable to any macromolecular compound in general and pharmacological macromolecular compounds in particular. For the purposes

of this invention, macromolecules have a molecular weight of at least 1000. The macromolecular pharmacological compounds of the invention are pharmacologically active in warm blooded animals including humans, and farm animals, or they are present, in compositions having pharmacological activity, e.g. for kidney dialysis.

The slow release composition of the Cardinal et al reference is a porous mix of chitosan. The preferred macromolecular compounds are proteins and polypeptides. In addition the Cardinal et al reference mentions polysaccharides, for example heparin and dextran as macromolecules. One skilled in the art would know that polysaccharides must have a structure which allows escape from the chitosan matrix. Therefore, if macromolecules are locked into the matrix, as they are in the presently claimed invention, it would be completely divergent to the invention described in the specification of the Cardinal et al reference. The heparin compound is a repetition of disaccharide units of D-glucosamine and uronic acid which is releasable from the chitosan matrix of the Cardinal et al reference. Dextran comprises glucose polymers which may or may not be branched. Large, heavily branched dextrans would not be released from the chitosan matrix. Therefore, it is unreasonable to presuppose that such dextrans or similar macromolecules, are included in the teachings or intended by the Cardinal et al patentees.

In distinction, the claimed invention comprises a matrix of chitosans and β -glucans. The β -glucans are locked into the chitosan structure and are unable to escape the matrix. As one skilled in the art would know, the side

chains of the β -glucan protrude out of the matrix and provide unique attributes of the currently claimed cosmetic preparation and are the result of the claimed methods.

It would be contrary to the teachings of the disclosure of the Cardinal et al reference to include or read in to the disclosure, any macromolecule, including β -glucans, which are unable to be released from the chitosan matrix. Therefore, the four corners of the complete disclosure of the Cardinal et al reference do not anticipate the currently claimed invention. The Examiner's interpretation of the Cardinal et al reference is contrary to the fundamental object of the Cardinal invention and would not be accepted by one skilled in the art. Therefore, the currently claimed invention is not anticipated by the Cardinal et al reference.

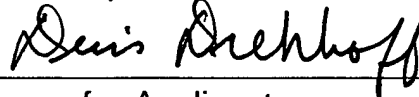
Claims 1-10 have been rejected under 35 U.S.C. §103(a) over the Cardinal et al reference in view of the Moriguchi et al reference in view of the Shikinami et al reference. The Examiner believes that the Cardinal et al and Shikinami et al references teach a film and reinforcement of film with fibers. As stated above, the Cardinal et al reference does not anticipate the currently claimed invention because of a basic misunderstanding of the Cardinal invention. Therefore, the Cardinal et al reference, since it is contrary to the currently claimed invention, cannot teach or suggest the claimed invention even when combined with another reference, whether it be the Shikanami et al reference or the Moriguchi et al reference. The Cardinal

reference teaches the releasability of macromolecule compounds from a chitosan matrix. The release of macromolecules from the currently claimed invention is impossible. This fact alone obviates the rejection under § 103 of the Patent Statutes in view of the Cardinal et al reference and any of the other cited references. The very same fact also obviates anticipation of the present claims in view of the Cardinal et al reference.

Applicants request a Notice of Allowance in view of the foregoing distinguishing comments of the claimed invention and the prior art references. The claims of the present invention are not anticipated by the Cardinal et al reference in view of the differences in the disclosure and the claimed invention. An early Notice of Allowance of the above-identified application is respectfully requested.

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Respectfully submitted,



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